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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/531,677

04/15/2005

Margaret Forney Prescott

PA/4-32723A

1716

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07/30/2009

NOVARTIS  
CORPORATE INTELLECTUAL PROPERTY  
ONE HEALTH PLAZA 104/3  
EAST HANOVER, NJ 07936-1080

EXAMINER

FRAZIER, BARBARA S

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

07/30/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/531,677	<b>Applicant(s)</b> PRESCOTT, MARGARET FORNEY	
	<b>Examiner</b> BARBARA FRAZIER	<b>Art Unit</b> 1611	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1 and 9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/18/09</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Status of Claims*

1. Claims 1 and 9 are pending in this application. Claims 2-8 and 10-18 stand canceled.
2. Claims 1 and 9 are examined.

### *Claim Rejections - 35 USC § 103*

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The rejection of claim 1 under 35 U.S.C. 103(a) as being unpatentable over Ross in view of Jordan et al is withdrawn in view of Applicant's arguments filed 3/18/09 that it would not be obvious to combine the teachings of Ross and Jordan et al.
5. The rejection of claim 9 under 35 U.S.C. 103(a) as being unpatentable over Ross in view of Jordan et al, and further in view of Duggan, is withdrawn in view of Applicant's arguments filed 3/18/09 that it would not be obvious to combine the teachings of Ross, Jordan et al, and Duggan.
6. The following rejection is newly applied:
7. **Claims 1 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Day et al (US 2001/0036936).**

The claimed invention is drawn to a method for the treatment of atherosclerosis in a patient in need of such treatment which comprises administering an effective amount of a bisphosphonate to the patient wherein the bisphosphonate is zoledronic or a pharmaceutically acceptable salt thereof or any hydrate thereof (see claim 1).

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Day et al teach methods for promoting bone formation and/or preventing bone loss and/or treating atherosclerosis with a composition comprised of a polyphosphonate (abstract). Preferred polyphosphonates include 1-hydroxy-2-(1H-imidazol-1-yl)ethylidene-1,1-bisphosphonic acid (zolendronate, which Applicants have identified as zoledronic acid) (see paragraphs 51 and 52 and claims 8 and 9). Day et al teach administration of effective amounts of the polyphosphonate (paragraphs 54-59).

Day et al do not specifically teach the use of zolendronate to treat atherosclerosis.

However, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to treat atherosclerosis by administering an effective amount of zolendronate; thus arriving at the claimed invention. One skilled in the art would be motivated to do so, with a reasonable expectation of success, because Day et al fairly teach and suggest treatment of atherosclerosis comprising administration of a polyphosphonate, and also fairly teach and suggest zolendronate as one of the preferred polyphosphonates. Therefore, one skilled in the art would find it obvious to select zolendronate from the finite list of identified, predictable solutions of the choice of polyphosphonate, with the reasonable expectation of treating atherosclerosis.

Regarding claim 9, Day et al teach that the polyphosphonate may be administered locally (paragraph 19).

### ***Conclusion***

No claims are allowed at this time.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to BARBARA FRAZIER whose telephone number is (571)270-3496. The examiner can normally be reached on Monday-Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BSF

/Sharmila Gollamudi Landau/  
Supervisory Patent Examiner, Art Unit 1611